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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,197	12/09/2003	Wayne P. Franco	0147-1 DIV2	5356

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/731,197	<b>Applicant(s)</b> FRANCO, WAYNE P.	
	<b>Examiner</b> Christopher J. Nichols, Ph.D.	<b>Art Unit</b> 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16,20-24,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16,20-24,27 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Status of Application, Amendments, and/or Claims***

1. The Response and Amendment filed 25 January 2005 has been received and entered in full.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections And/Or Rejections***

3. The Objections to the Specification as set forth at pp. 2 ¶3 in the previous Office Action (25 October 2004) is *withdrawn* in view of Applicant's amendments (25 January 2004).
4. The Rejection of claims **16, 24, and 31** under 35 U.S.C. §112 ¶2 as set forth at pp. 2 ¶4 in the previous Office Action (25 October 2004) is *withdrawn* in view of Applicant's amendments (25 January 2004).
5. The Rejection of claim **31** under 35 U.S.C. §102(a) as set forth at pp. 3 ¶5-6 in the previous Office Action (25 October 2004) is *withdrawn* in view of Applicant's amendments (25 January 2004).
6. The Rejection of claims **16, 22, 31, and 35** under 35 U.S.C. §102(b) as set forth at pp. 3-4 ¶7-8 in the previous Office Action (25 October 2004) is *withdrawn* in view of Applicant's amendments (25 January 2004).
7. The Rejection of claims **31, 32, and 35** under 35 U.S.C. §102(b) as set forth at pp. 4 ¶9-10 in the previous Office Action (25 October 2004) is *withdrawn* in view of Applicant's amendments (25 January 2004).
8. The Rejection of claims **16-35** under 35 U.S.C. §103(a) as set forth at pp. 4-6 ¶11-16 in the previous Office Action (25 October 2004) is *withdrawn* in view of Applicant's amendments (25 January 2004).

***New Rejections As Necessitated by Amendment***

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

### ***Statutory Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 16, 20-24, and 27-28 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 4, 5, 11, 12, 13, 14, 15, and 20 of U.S. Patent No. 6,759,386 (6 July 2004) Franco. This is a double patenting rejection.

10. The claims of the instant application and US '386 encompass treatment of a patient displaying the symptoms of acute coronary artery disease and chronic coronary artery disease. As noted in the previous Office Action (25 October 2004), the Examiner failed to find an art-accepted definition for "acute coronary artery disease" in the NIH MeSH National Library of Medicine database, [www.dictionary.com](http://www.dictionary.com), and the University of Newcastle upon Tyne's On-Line Medical Dictionary. Therefore, the Examiner treated "acute coronary artery disease" as "coronary artery disease", the most relevant and art-accepted term encompassed by the limitation. Applicant did not traverse this definition in the Response filed (25 January 2005) but amended "acute coronary artery disease" to "coronary artery disease" and as such has accepted

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the Examiner's definition of the term. And therefore, the independent claims of the instant Application and US '386 encompass the same patient population.

11. In addition, both the instant application and US '386 teach practicing the methods using the identical method steps and using the identical agents (FGF-1, FGF-2, VEGF, and mixtures thereof) assessing the treatment via CPK-MB measurement thus meeting the limitations of claims 16 and 24. Both the instant application and US '386 teach practicing the methods using a dry powder formulation or a liquid aerosol formulation thus meeting the limitations of claims 20, 21, 27, and 28. Both the instant application and US '386 teach practicing the methods wherein the symptoms of acute coronary artery disease, chronic coronary artery disease, or coronary artery disease (all held to encompass one another) are brought on by reperfusion injury and wherein said reperfusion injury is induced by a procedure selected from the group consisting of thrombolytic therapy, bypass surgery, and angioplasty thus meeting the limitations of claims 22 and 23. Both the instant application and US '386 teach practicing the methods wherein the symptoms of acute coronary artery disease, chronic coronary artery disease, or coronary artery disease (all held to encompass one another) are brought on by a condition selected from the group consisting of myocardial infarct, unstable angina, an acute anginal attack, and reperfusion injury thus meeting the limitations of claims 22.

12. The body of the claims fully and intrinsically sets forth all of the limitations of the claimed invention. Further, MPEP §806.03 states that inventions which share the same essential characteristics, in the instant case with regards to methods, the same patient population and the same method steps and achieve the same goal, are held to be patentably indistinct.

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13. The Examiner notes that a Restriction Requirement was set forth in the parent Application (09/828330) on 6 June 2002. The Examiner holds the Restriction Requirement to be in error for restricting on grounds of the preamble and not the method steps (see MPEP §808.01). Also, Application failed to traverse and distinctly point out the errors in the time of filing the response (8 July 2002). Since the Restriction Requirement was in error, Applicant failed to traverse, Applicant has cleared amended the instant claims into the same Group as originally presented, the provisions against double-patenting are not applicable [see *Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 784 F.2d 351, 228 USPQ 837 (Fed. Cir. 1986), the Court held that “35 U.S.C. §121 of course does not provide that multiple patents may be granted on the identical invention.”]

14. In conclusion, as instantly amended, the instant Application and US ‘386 claim the same, non-distinct, non-independent invention treating chronic and acute coronary artery disease via administration of FGF-1, FGF-2, VEGF, mixtures thereof, monitoring for effect, and treating accordingly (see MPEP §804.01).

### ***Summary***

15. No claims are allowed.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **<http://pair-direct.uspto.gov>**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

April 29, 2005

A large, stylized handwritten signature in black ink, likely belonging to Christopher James Nichols, the examiner mentioned in the text. The signature is written in a cursive, flowing style with a large initial 'C'.